UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/737,633	11/15/96	SAMARITANI F	F/42-60

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OSTROLENK FABER GERB & SOFFEN
1180 AVENUE OF THE AMERICAS
NEW YORK NY 10036-8403

EXAMINER	
FITZGERALD, D	
ART UNIT	PAPER NUMBER
1646	10

DATE MAILED: 03/19/98

Please find ~~below~~ attached a communication from the EXAMINER in charge of this application.

Commissioner of Patents

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COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☐ THE PERIOD FOR RESPONSE:

a) ☐ is extended to run _____ or continues to run _____ from the date of the final rejection

b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition , and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☒ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed 02 Mar 98 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

   a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.

   b. ☐ They raise new issues that would require further consideration and/or search. (See Note).

   c. ☐ They raise the issue of new matter. (See Note).

   d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

   e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: _____

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing an appeal, the proposed amendment ☒ will be entered ☐ will not be entered and the status of the claims will be as follows:

   Claims allowed: NONE
   Claims objected to: NONE
   Claims rejected: 1, 3-10

   However;

   ☒ Applicant's response has overcome the following rejection(s): §112, second paragraph.

4. ☒ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because See attached.

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficent reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

As part of an Office-wide administrative reorganization effective February 1998, Art Unit 1812 has become Art Unit 1646. To aid the Office in matching papers, please use the new Art Unit number, 1646, on all correspondence relating to this application.

The amendment filed 2 March 1998 has been entered in part. The substitute pages corresponding to pages 1, 2, and 3 of the specification have not been entered because they contain extraneous marks ("✓ submitted") which were not present in the application as filed. The requirement for legible substitute pages is maintained.

The amendments to the claims have been entered and are effective to obviate the outstanding rejection under 35 U.S.C. § 112, second paragraph.

Applicant argues that Cymbalista fails to teach that mannitol fails to stabilize IFN-β. The examiner has reviewed Cymbalista and finds that applicant is correct on this point: mannitol is only described as an "excipient" which is suitable for the formulation of the cytokine. As Hershenson provides the teaching that mannitol does in fact stabilize IFN-β, however, the absence of such teaching from Cymbalista does not materially change the nature of the teachings provided by the prior art references considered collectively.

Applicant urges that attribution of the teaching that mannitol stabilizes IFN-β to Hershenson "is an overstatement of the disclosure in this reference." What Hershenson teaches is that "[t]he compositions [of the invention] can further comprise an additional stabilizing agent, such as a carbohydrate, for example . . . mannitol, . . . [or] human serum albumin (HSA) which can be used alone or in combination with a carbohydrate stabilizing agent." Hershenson at col. 9, lines 21-27. The examiner can find no overstatement in his observation. While it is true, as applicant urges, that Hershenson's invention involves compositions which comprise glycerol or PEG as the primary stabilizer, the unambiguous teachings of the reference fairly suggest that either mannitol or HSA, alone or in combination, would reasonably be expected to stabilize IFN-β in the absence as well as the presence of glycerol or PEG. That the inclusion of one of the latter compounds is the invention which Hershenson *claims* does not operate to negate the other teachings which are present in the reference. As to the silence of the reference on the use of formulations which lack glycerol or PEG, the Office observes only that the reference provides no

evidence which teaches that IFN-β would *not* be stable absent such components and does not take the position, as applicant appears to consider, that its silence is tantamount to a teaching which actually advocates their omission.

Finally, applicant considers that the description of mannitol as a polyol constitutes hindsight and should not factor into the Office's analysis. As was implicit in the previous action, Official notice is taken that "polyol" was a term of art in common use at the time of the invention; that it was defined as describing organic compounds having a plurality ("poly") of alcohol (-OH, "ol") functional groups; that the structure of mannitol was known in the art at the time of invention; and that mannitol does in fact comprise six -OH groups. In any event, as the term "polyol" is no longer recited in any of the claims, this point is of at most minor relevance to the rejection at issue.

DAVID L. FITZGERALD
PRIMARY EXAMINER
ART UNIT 1646

Tel. (703) 308-3934
Fax (703) 308-0294

18 March 1998